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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,965	03/31/2004	Robert Falotico	CRD-5073 NP	7706

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EXAMINER	
KIM, JENNIFER M	
ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
10/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/813,965	FALOTICO ET AL.	
	Examiner	Art Unit	
	Jennifer Kim	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-5,9 and 10* is/are pending in the application.

4a) Of the above claim(s) *9 and 10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on August 16, 2007 has been entered.

Response to Arguments

Applicants' arguments with respect to claims 1 and 3-5 have been considered but are moot in view of the new ground(s) of rejection.

Claim Objections

Claim 3 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicants are required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The concentration of rapamycin set forth in claim 3 is broader than the previous claim which it depends from. Therefore, claim 3 is not further limiting the subject matter of the previous claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sehgal (EP 0041795 A2) of record in view of Myers (U.S.Patent No. 5,891,845).

Sehgal teaches an injectable composition of rapamycin, suitable for intravenous administration comprising about 1 to 20mg/ml of rapamycin composition and nonionic surfactants. (page 19, claim 1). This concentration range encompasses Applicants' range set forth in claims 1 and 3. Sehgal teaches that the rapamycin composition is prepared by dissolving rapamycin in an organic solvent which is capable of dissolving rapamycin and is miscible with the nonionic surfactant such as ethanol, and adding the nonionic surfactant, if required, removing some or all of the organic solvent, and adding water. (page 6, line 4- page 7, line 5). Sehgal illustrates the preparation of an injectable rapamycin composition by removing ethanol by evaporation. (page 8, example 1, claim 7). Sehgal teaches that various surfactant can be employed in the composition. (page 3, claim 9).

Sehgal do not teach the amount of ethanol and vitamin E TPGS set forth in claim 1.

Myers teaches TPGS is known as a surface active agent derived from a natural source of vitamin E and believed to be a bioavailability enhancer and utilized in various formulations. (column 7, lines 13-65).

It would have been obvious to one of ordinary skill in the art to incorporate vitamin E TPGS in Sehgal's rapamycin formulation because Sehgal teaches that various surfactants can be added in the formulation and because Myers teaches that TPGS is known surfactant utilized in various formulations. One would have been motivated to make such modification in order to achieve enhanced bioavailability of rapamycin by adding surfactant such as TPGS taught by Myers as a bioavailability enhancing surfactant. There is a reasonable expectation of successfully formulating rapamycin together with TPGS because Sehgal teach that various surfactants can be employed in rapamycin formulation and vitamin E-TPGS provides enhanced bioavailability of rapamycin. With regard to an ethanol content of less than 2%, such is obvious because Sehgal illustrates removing ethanol by evaporation upon the dissolution of rapamycin in the process of preparing the injectable formulation of rapamycin. Sehgal teaches that some or all of the ethanol content can be removed once the dissolution of rapamycin takes place. Therefore, the ethanol content of less than 2% is encompassed by the evaporation step taught by Sehgal et al.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sehgal (EP 0041795 A2) of record in view of Myers (U.S.Patent No. 5,891,845) as applied to

claims 1, 3 and 4 above, and further in view of Cooperstone et al. (U.S.Patent No. 7,060,709 B2) of record.

The teachings of Sehgal and Myers as applied as before.

Sehgal and Myers do not teach CCI-779.

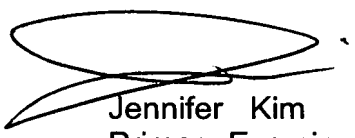
Copperstone et al. teach that CCI-779 is a rapamycin 42-ester with 3-hydroxy-2-(hydroxymethyl)-2-methylpropionic acid and can be formulated in an injectable composition. (abstract, column 1, lines 61-67). Cooperstone et al. teach that that use of a surfactant with diluents is advantageous in the CCI-779 parenteral formulation because it prevents precipitation of CCI-779 upon dilution with aqueous infusion solutions or blood. (column 7, lines 7-14).

It would have been obvious to one of ordinary skill in the art to employ rapamycin compound such as CCI-779 in Sehgal's formulation as modified by Myers because Copperstone et al. teach that CCI-779 is a rapamycin 42-ester with 3-hydroxy-2-(hydroxymethyl)-2-methylpropionic acid and can be formulated in an injectable composition. One would be motivated to make such modification in order to achieve an expected benefit of stability of CCI-779 with surfactant and diluents contained in Sehgal's composition as modified by Myers preventing precipitation of CCI-779.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Jennifer Kim
Primary Examiner
Art Unit 1617

Jmk
October 1, 2007